EC Declaration of Conformity

Manufacturer:

Name: Inzek International Trading B.V.
Address: Laan van de Ram 49, 7324BW – Apeldoorn – The Netherlands

This declaration of conformity is issued under the sole responsibility of the legal manufacturer Inzek International Trading B.V.

Product Name and Models(s):

Name: Vitamin D Rapid Test (Fingerstick Whole Blood)

Model: Cassette

REF: RVD-402S

EDMA Code: 12 07 02 90 00

Classification:

After following the classification rules of Annex II of the COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices, the device listed in this declaration was classified as a non-listed in vitro diagnostic medical device.

Conformity statement:

According to Article 9 of the COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices, and based on the classification of the product, the manufacturer, in order to affix the CE marking, followed the procedure referred to in Annex III, of the directive.

Notified body:

Not applicable, as a non-listed in vitro diagnostic medical device does not require the involvement of a Notified Body

Place, Date of Issue: Apeldoorn on 27/05/2021

Signature:

Name: Z. Hamid

Position: Manager